

PTO/SB/26 (09-04)
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**TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING
REJECTION OVER A "PRIOR" PATENT**

Docket Number (Optional)
DURE-007CON2

In re Application of: JOHNSON et al.

Application No.: 10/719,007

Filed: 20 November 2003

For: DEVICES AND METHODS FOR PAIN MANAGEMENT

The owner*, DURECT CORPORATION, of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term **prior patent** No. 6,835,194 as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said **prior patent** is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

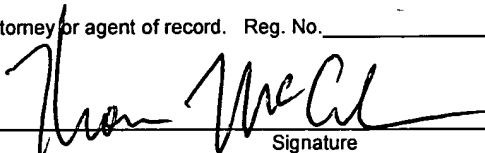
- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☒ For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☐ The undersigned is an attorney or agent of record. Reg. No. _____



Signature

21 December 2005

Date

Thomas P. McCracken (Reg. No. 38,548)

Typed or printed name

408-777-4915

Telephone Number

- ☒ Terminal disclaimer fee under 37 CFR 1.20(d) included.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

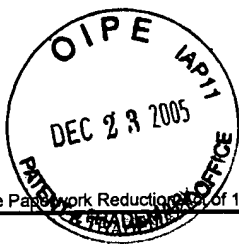
*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

This collection of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: DURECT Corporation

Application No./Patent No.: US 6,835,194 B2 Filed/Issue Date: 28 December 2004

Entitled: IMPLANTABLE DEVICES AND METHODS FOR TREATMENT OF PAIN BY DELIVERY OF FENTANYL AND FENTANYL CONGENERS

DURECT Corporation, a corporation
(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or
2. ☐ an assignee of less than the entire right, title and interest
(The extent (by percentage) of its ownership interest is _____ %)

in the patent application/patent identified above by virtue of either:

A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 13267, Frame 149-152, or for which a copy thereof is attached.

OR

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.
2. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.
3. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

☐ As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

Thomas P. McCracken
Signature

21 December 2005
Date

Thomas P. McCracken (Reg. No. 38,548)
Printed or Typed Name

408-777-4915
Telephone Number

Chief Patent Counsel
Title

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PTO/SB/96 (11-05)

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STATEMENT UNDER 37 CFR 3.73(b)Applicant/Patent Owner: DURECT CorporationApplication No./Patent No.: 10/719,007 Filed/Issue Date: 20 November 2003Entitled: DEVICES AND METHODS FOR PAIN MANAGEMENTDURECT Corporation, a corporation
(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or
2. ☐ an assignee of less than the entire right, title and interest
(The extent (by percentage) of its ownership interest is _____ %)

in the patent application/patent identified above by virtue of either:

A ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

OR

B ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

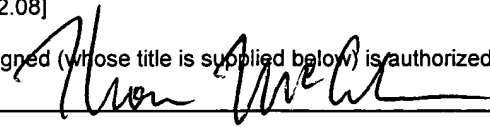
1. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.
2. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.
3. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

☐ As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

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The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.



Signature

21 December 2005

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Thomas P. McCracken (Reg. No. 38,548)

Printed or Typed Name

408-777-4915

Telephone Number

Chief Patent Counsel

Title

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**ASSIGNMENT OF APPLICATION
(JOINT)**

Address to:

Box Assignment

Assistant Commissioner for Patents
Washington, D.C. 20231

Attorney Docket Number DURE-007

First Named Inventor Johnson, et al.

Application Number 09/522,535

Filing Date March 10, 2000

Examiner Name N/A

Group Art Unit 1614

Title Devices and Methods for Pain Management

THIS ASSIGNMENT, by Randolph Mellus Johnson and Felix Theeuwes (hereinafter referred to as the assignors), residing at Half Moon Bay, California and Los Altos Hills, California respectively, witnesseseth:

WHEREAS, the said assignors have invented certain new and useful improvements in Devices and Methods for Pain Management

X for which an application for a United States Patent was filed on March 10, 2000, Application No. 09/522,535.

— for which an application for a United States Patent was executed on —, and

WHEREAS, Durect Corporation a corporation duly organized under and pursuant to the laws of California, and having its principal place of business at 10240 Bubb Road, Cupertino, California 95014-4166 (hereinafter referred to as the assignee) is desirous of acquiring the entire right, title and interest in and to said invention and said application for Letters Patent of the United States, and in and to any Letters Patent or Patents, United States or foreign, to be obtained therefor and thereon:

NOW THEREFORE, in consideration of One Dollar (\$1.00) and other good and sufficient considerations, the receipt of which is hereby acknowledged, said assignors have sold, assigned, transferred and set over, and by these presents do sell, assign, transfer and set over, unto the assignee, its successors, legal representatives and assigns, the entire right, title and interest in and to the above-mentioned invention, application for Letters Patent, and any and all Letters Patent or Patents in the United States of America and all foreign countries which may be granted therefor and thereon, and in and to any and all divisions, continuations, and continuations-in-part of said application, or reissues or extensions of said Letters Patent or Patents, and all rights under the International Convention for the Protection of Industrial Property, the same to be held and enjoyed by said assignee, for its own use and behoof and the use and behoof of its successors, legal representatives and assigns, to the full end of the term or terms for which Letters Patent or Patents may be granted, as fully and entirely as the same would have been held and enjoyed by the assignors, had this sale and assignment not been made.

AND for the same consideration, said assignors hereby covenant and agree to and with said assignee, its successors, legal representatives and assigns, that, at the time of execution and delivery of these presents, said assignors are the sole and lawful owners of the entire right, title and interest in and to said invention and the application for Letters Patent above-mentioned, and that the same are unencumbered and that said assignors have good and full right and lawful authority to sell and convey the same in the manner herein set forth.

AND for the same consideration, said assignors hereby covenant and agree to and with said assignee, its successors, legal representatives and assigns, that said assignors will, whenever counsel of said assignee, or the counsel of its successors, legal representatives and assigns, shall advise that any proceeding in connection with said invention, or said application for Letters Patent, or any proceeding in connection with Letters Patent for said invention in any country, including interference proceedings, is lawful and desirable, or that any division, continuation or continuation-in-part of any application for Letters Patent or any reissue or extension of any Letters Patent, to be obtained thereon, is lawful and desirable, sign all papers and documents, take all lawful oaths, and do all acts necessary or required to be done for the procurement, maintenance, enforcement and defense of Letters Patent for said invention, without charge to said assignee, its successors, legal representatives and assigns, but at the cost and expense of said assignee, its successors, legal representatives and assigns.

AND said assignors hereby request the Commissioner of Patents to issue said Letters Patent of the United States to said assignee as the assignee of said invention and the Letters Patent to be issued thereon for the sole use and behoof of said assignee, its successors, legal representatives and assigns.

Date 6/6/00

Name of Inventor

Randolph Mellus Johnson
Randolph Mellus Johnson

Date June 6, 00

Name of Inventor

Felix Theeuwes
Felix Theeuwes

CALIFORNIA ALL-PURPOSE ACKNOWLEDGMENT

State of California

County of Santa Clara

SS.

On June 6, 2000, before me, Keron Marie MacDonald

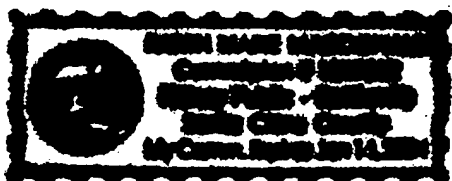
Name and Title of Officer (e.g., "Jane Doe, Notary Public")

personally appeared Baroldpt Adellus Johnson & Felix Hernandez

Name(s) of Signer(s)

- ☒ personally known to me
☐ proved to me on the basis of satisfactory evidence

to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.



Place Notary Seal Above

WITNESS my hand and official seal.

Keron Marie MacDonald
Signature of Notary Public

OPTIONAL

Though the information below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent removal and reattachment of this form to another document.

Description of Attached Document

Title or Type of Document: Assignment of Joint Application

Document Date: 3/10/2000 (Filing Date) Number of Pages: 3

Signer(s) Other Than Named Above: None

Capacity(ies) Claimed by Signer

Signer's Name: _____

- ☐ Individual
☐ Corporate Officer — Title(s): _____
☐ Partner — ☐ Limited ☐ General
☐ Attorney in Fact
☐ Trustee
☐ Guardian or Conservator
☐ Other: _____

Signer Is Representing: _____

RIGHT THUMBPRINT
OF SIGNER
Top of thumb here